UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

* * *

JACQUE ALLEN,

Plaintiff,

v.

ZIMMER HOLDINGS, INC., a foreign corporation; ZIMMER, INC., a foreign corporation; ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC., a foreign corporation; STRYKER HOLDINGS, LLC, a domestic limited liability company; STRYKER CORPORATION, a foreign corporation; HOWMEDICA OSTEONICS CORP., a foreign corporation, doing business as STRYKER ORTHOPAEDICS; ABC CORPORATIONS II-X; BLACK AND WHITE COMPANIES II-X; and JOHN DOES II-X, inclusive,

Defendants.

3:15-CV-00341-LRH-VPC

ORDER

Before the Court is Defendants Stryker Corporation and Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics' (collectively, "Stryker") Motion to Dismiss Plaintiff Jacque Allen's ("Allen") First Amended Complaint ("FAC"). Doc. #7.[1] Allen filed an Opposition, which included a request for leave to amend (Doc. #19), to which Stryker replied (Doc. #21).

I. Factual Background

This case involves strict product liability, negligence, and breach of implied and express warranty claims that arose out of the implantation of an artificial hip prosthesis manufactured by

[1] Refers to the Court's docket number.

Defendants Zimmer Holdings, Inc.; Zimmer, Inc.; and Zimmer Orthopaedic (collectively, "Zimmer") and the use of Stryker's Surgical Simplex P Radiopaque Bone Cement ("Simplex") and Howmedica Sterile R Log Medium Bone Plug ("Bone Plug").

On or about June 17, 2008, Allen underwent hip surgery utilizing products produced by the defendants. After benefiting from the right hip replacement for several years, Allen began experiencing groin pain in late 2012. Allen consulted with her orthopedic surgeon who suspected that the site of the right hip prosthesis was "loose." On January 8, 2013, Allen was seen by another orthopedic surgeon, Dr. Jackson Jones, who recommended revision of the femoral component. Revision of the right total hip procedure was conducted on February 24, 2013.

On February 13, 2015, Allen filed an action in the Second Judicial District Court for the State of Nevada in and for the County of Washoe. Doc. # 1 Ex. 2. She filed her First Amended Complaint on June 10, 2015. Doc. #1 Ex. 1. The case was removed to federal court. On July 7, 2015, Stryker filed its Motion to Dismiss. Doc. #7. Allen responded on August 3, 2015. Doc. #19. Stryker filed a Reply on August 7, 2015. Doc. #21.

II. Legal Standard

Stryker seeks dismissal for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). To survive a motion to dismiss for failure to state a claim, a complaint must satisfy the Federal Rule of Civil Procedure 8(a)(2) notice pleading standard. *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1103 (9th Cir. 2008). That is, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The 8(a)(2) pleading standard does not require detailed factual allegations, but a pleading that offers "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action'" will not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

To satisfy the plausibility standard, 8(a)(2) requires a complaint to "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). A claim has facial plausibility when the pleaded factual

content allows the Court to draw the reasonable inference, based on the Court's "judicial experience and common sense," that the defendant is liable for the misconduct alleged. *See id.* at 678-79. The plausibility standard "is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* at 678 (internal quotation marks omitted).

In reviewing a motion to dismiss, the court accepts the facts alleged in the complaint as true. *Id.* The "factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011). Moreover, "bare assertions . . . amount[ing] to nothing more than a formulaic recitation of the elements of a . . . claim . . . are not entitled to an assumption of truth." *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009) (citing *Iqbal*, 556 U.S. at 681) (brackets in original) (internal quotation marks omitted). The court discounts these allegations because "they do nothing more than state a legal conclusion—even if that conclusion is cast in the form of a factual allegation." *Id.* (citing *Iqbal*, 556 U.S. at 681). "In sum, for a complaint to survive a motion to dismiss, the non-conclusory 'factual content,' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." *Id.*

Before trial, a party can amend its complaint twenty-one days after serving it or twenty-one days after service of a responsive pleading or motion to dismiss under Rule 12(b)(6). Fed. R. Civ. P. 15(a)(1). The court can also grant leave to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2). If the court grants a motion to dismiss, "[t]he standard for granting leave to amend is generous." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 701 (9th Cir. 1990). The Court will generally only decline to grant leave to amend if the party opposing amendment shows "bad faith, undue delay, prejudice to the opposing party, futility of amendment," or that the plaintiff has previously amended the complaint without healing its defects. *United States v.*

Corinthian Colls., 655 F.3d 984, 995 (9th Cir. 2011) (citing *Johnson v. Buckley*, 356 F.3d 1067, 1077 (9th Cir. 2004)).

III. Discussion

A. Premarket Approval and Federal Preemption

a. Premarket Approval

Stryker argues that Allen's claims are preempted by the Medical Device Amendments ("MDA") of 1976 to the Federal Drug and Cosmetic Act. The MDA grants the Federal Drug Administration ("FDA") regulatory authority over medical devices and defines three tiers of regulation. 21 U.S.C. § 360c. The three regulatory tiers correspond to the inherent risk of using the device, with Class III representing the greatest level of risk. *See Riegel v. Medtronic, Inc*., 552 U.S. 312, 128 S.Ct. 999, 1003, 169 L.Ed.2d 892 (2008). Developers of new Class III devices are required to obtain premarket approval ("PMA"), the FDA's highest level of oversight. *Id*. at 1003–1004, 21 U.S.C. § 360c(a)(1)(C). Simplex, one of the products at issue here, was developed prior to the MDA and went through the FDA's New Drug Application ("NDA") process. When the MDA came into effect, devices such as Simplex, which had been treated as drugs prior to the amendments to the 1938 Act, were automatically reclassified as Class III medical devices. *See* 21 U.S.C. § 360j(l)(1). The MDA provided that these devices were deemed to have PMA approval if they had gone through the NDA approval process. *Id*. at § 360j(l)(3)(A). Beginning in 1976 Simplex was accordingly treated as a Class III medical device with PMA approval.

In 2002, the FDA re-classified Simplex as a Class II medical device. This change does not affect the analysis here because preemption analysis focuses on how the product came to market, not its current classification. *In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig.*, 592 F. Supp. 2d 1147, 1156 (D. Minn. 2009) *aff'd sub nom. In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) and *aff'd sub nom. In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) "[P]reemption necessarily looks *backward* (to the time of PMA) rather than *forward*" because retroactive second-guessing on the FDA's decision-making would interfere with the PMA

process. *Id.* Thus, Simplex is still treated as having PMA approval for the purposes of MDA preemption analysis.

Additionally, the Bone Plug used with Simplex is considered to have been approved through the PMA process. Component parts, like the Bone Plug, are considered to have the same PMA approval as the device of which they are a component. *Cornwell v. Stryker Corp.*, 2010 WL 4641112 (D. Idaho Nov. 1, 2010); *Lewkut v. Stryker Corp*., 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010); *Riley v. Cordis Corp.* 625 F. Supp. 2d 769, 779-80 (D. Minn. 2009). Thus both Simplex and the Bone Plug are considered to have PMA approval for the purposes of MDA preemption analysis.

b. Federal Preemption

Along with providing a regulatory framework for medical devices, Congress included a preemption clause in the MDA that states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel*, the Supreme Court held § 360k(a) preempts a number of common law claims stemming from the failure of a Class III device. *Riegel*, 552 U.S. at 321. The Court established a two-pronged test for claim preemption under § 360k(a). *Id*. First, courts must determine if the federal government has established requirements relating to the device. *Id*. If so, courts then evaluate whether a state claim imposes requirements relating to the safety and effectiveness of the device that are "different from, or additional to," federal requirements. *Id*.

The Supreme Court held that the FDA's premarket approval process "imposes requirements under the MDA" for Class III devices, satisfying the first prong of the test. *Id*. at 1007 (internal quotations omitted). Therefore, it is the second prong of the *Riegel* test that is

often determinative; specifically, whether the claims relate to the safety and effectiveness of the device. *Horn v. Boston Scientific Neuromodulation Corp.*, No. CV409-074, 2011 WL 3893812, at *4 (S.D. Ga. Aug. 26, 2011. In *Riegel*, the Court concluded that common law claims for negligence, strict liability, and breach of implied warranty are examples of state law "requirements" that relate to the safety or effectiveness of a device, and are thus preempted. *Riegel*, 552 U.S. at 322-26. This is because "[s]tate tort law that requires a [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme," and is preempted. *Id*. at 1008.

Additionally, *Riegel* also introduced the concept of "parallel claims," which provide a narrow exception to MDA preemption. *Riegel*, 552 U.S. at 329. The Court explained that state claims based on a violation of FDA regulations are not preempted under the MDA. *Id*. The Court reasoned that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to,' the requirements imposed by federal law." *Id*. (quoting § 360k(a)(1)). Thus, purposely pled state claims based on violations of FDA regulations are not preempted by § 360k(a), as those claims do not conflict with, but rather parallel, the statutory scheme. *Id*. 'To properly plead parallel claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation.'" *Martin v. Medtronic, Inc*., 32 F. Supp. 3d 1026, 1034 (D. Ariz. 2014) (quoting *Eidson v. Medtronic, Inc*., —— F.Supp.3d ——, ——, 2014 WL 1996024, at *7 (N.D.Cal.2014)).

The question of whether MDA preemption applies to claims involving the breach of express warranties has not been decided by the Supreme Court. Courts have held claims for breach of express warranty to be preempted primarily where the warranty directly relates to the safety or effectiveness of the device. *See Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *10 (N.D. Ga. Aug. 19, 2011) (holding that a claim for breach of express warranty that a device was "safe and highly reliable" would conflict with the FDA's conclusion the device was "reasonably safe and effective" and is thus preempted); *In re Medtronic, Inc.*, 592 F.Supp.2d 1147, 1164 (D. Minn. 2009) (holding that claims for breach of an express warranty of

a medical device's safety would require a jury to determine that the device was unsafe); *Miller v. DePuy Spine, Inc.*, 638 F.Supp.2d 1226, 1230 (D. Nev. 2009) (holding that a breach of express warranty claim was preempted where an essential element of the claim includes "proof that a device granted a [PMA] is not safe or effective"). This differs from something like a voluntarily imposed limited warranty guaranteeing craftsmanship, a type of express warranty some courts have found not to be preempted. *Cline v. Advanced Neuromodulation Sys., Inc.*, 914 F. Supp. 2d 1290, 1298 (N.D. Ga. 2012); *Horn*, 2011 WL 3893812, at *.

Allen's complaint does not contain adequate allegations to survive MDA preemption. Because the products at issue are deemed to have PMA approval, requirements are imposed under the MDA, and the first prong of the *Riegel* test is met; however, Allen fails at the second prong. To satisfy the second prong, the state claims must impose requirements relating to safety and effectiveness that are different from or additional to the federal requirements. Here, Allen's product liability, negligence, and implied warranty claims are based on the safety and effectiveness of the Simplex and Bone Plug, and thus are preempted by the MDA. Nothing in Allen's complaint indicates her state claims are based on anything different from, or additional to, the federal requirements. Allen instead relies on general claims based on common law duties challenging the safety and effectiveness of Simplex and the Bone Plug. Allen makes no arguments and provides no information as to how her claims parallel federal requirements or how she might fit into this narrow exception. None of her claims even mention FDA regulations, much less show an alleged violation of FDA regulations or establish a causal nexus between the injury and the violation. Additionally, Allen's express warranty claim also seems to be premised on the general safety and effectiveness of the Simplex and Bone Plug, as opposed to something like the limited craftsmanship warranties found in *Cline* and *Horn*, and would thus be preempted, as well. Therefore, Allen does not demonstrate a claim that is not preempted by the MDA. However, the Court will grant Allen's request for leave to amend her complaint.

B. Statute of Limitations

Stryker argues that Allen's claims are barred by the statute of limitations even if they were tolled because the two year period would have expired at the latest in January of 2015, two

years after revision surgery was recommended. Allen does not dispute the two year statute of limitations but counters that the finder of fact should determine the applicable statute of limitations period for a given case.

NRS 11.190(4)(e) provides a two-year statute of limitations for "an action to recover damages for injuries to a person or for the death of a person caused by the wrongful act or neglect of another." This applies whether the claim is articulated as negligence, breach of contract, tort, or product liability. *Sparks v. Alpha TauOmega Fraternity, Inc.*, 127 Nev ——, —— , n. 4, 255 P.3d 238, 243 n. 4 (2011) (applying NRS 11.190(4)(e) to a negligence personal injury claim); *Meadows v. Sheldon Pollack Corp.*, 92 Nev. 636, 637, 556 P.2d 546, 546 (explaining that although the plaintiff alleged breach of contract, "the gravamen of his cause of action is in tort to recover damages for personal injuries; thus, the two-year limitation of NRS 11.190(4)(e) is applicable"); *Blotzke v.Christmas Tree, Inc.*, 88 Nev. 449, 450, 499 P.2d 647, 647 (1972) (holding that a contract claim for personal injury is treated as a tort claim and the two year state of limitations applies); *Bender v. Clark Equipment Co.* 111 Nev. 844, 897 P.2d 208, 208 (1995) (stating plaintiff filed his strict product liability case two days before the two-year statute of limitations period had run).

"[A] cause of action accrues when the wrong occurs and a party sustains injuries for which relief could be sought." *Petersen v. Bruen*, 106 Nev. 271, 274, 792 P.2d 18, 20 (1990). However, the discovery rule tolls "the statutory period of limitations ... until the injured party discovers or reasonably should have discovered facts supporting a cause of action." *Id.* This rule requires a plaintiff to use due diligence in determining the existence of a cause of action and delays the accrual of the cause of action until the plaintiff obtains inquiry notice. *Bemis v. Estate of Bemis*, 114 Nev. 1021, 1025, 967 P.2d 437, 440 (1998). Inquiry notice occurs when a plaintiff "should have known of facts that 'would lead an ordinarily prudent person to investigate the matter further.'" *Winn v. Sunrise Hosp. & Med. Ctr.*, 128 Nev. ——, ——, 277 P.3d 458, 462 (2012) (quoting *Black's Law Dictionary* 1165 (9th ed. 2009)). Factual knowledge "need not pertain to precise legal theories the plaintiff may ultimately pursue, but merely to the plaintiff's general belief that someone's negligence may have caused his or her injury." *Id.* Moreover,

"[d]ismissal on statute of limitations grounds is only appropriate 'when uncontroverted evidence irrefutably demonstrates plaintiff discovered or should have discovered' the facts giving rise to the cause of action." *Bemis*, 114 Nev. at 1025, 967 P.2d at 440 (quoting *Nevada Power Co. v. Monsanto Co.*, 955 F.2d 1304, 1307 (9th Cir.1992)).

Here, the fact that Allen's orthopedic surgeons suspected the right hip prosthesis was loose and recommended revision surgery simply does not rise to the high level of "uncontroverted evidence" irrefutably demonstrating Allen should have discovered the facts giving rise to her cause of action. Because there was no irrefutable evidence that Allen was on inquiry notice, this Court declines to dismiss her complaint on statute of limitations grounds.

IV. Conclusion

IT IS THEREFORE ORDERED that Stryker's Motion to Dismiss (Doc. #7) is DENIED.

IT IS FURTHER ORDERED that Allen's request for leave to amend (Doc. #19) is GRANTED. If Allen chooses to file an amended complaint, such complaint shall be filed within thirty (30) days of the entry of this order.

IT IS FURTHER ORDERED that if no amended complaint is filed within the thirty (30) days allotted, the Clerk of the Court shall enter the final dismissal of this action.

IT IS SO ORDERED.

DATED this 30th day of October 2015.

LARRY R. HICKS
UNITED STATES DISTRICT JUDGE